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Research Article

Pedicle screw augmentation with bone cement enforced Vicryl mesh†

Running title: Pedicle screw augmentation with cemented mesh

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Abstract

Achieving sufficient mechanical purchase of pedicle screws in osteoporotic or previously instrumented bone is technically and biologically challenging. Techniques using different kinds of pedicle screws or methods of cement augmentation have been used to address this challenge, but are associated with difficult revisions and complications. The purpose of this biomechanical trial was to investigate the use of biocompatible textile materials in combination with bone cement to augment pullout strength of pedicle screws while reducing the risk of cement extrusion. Pedicle screws (6/40mm) were either augmented with standard bone-cement (Palacos LV+G) in one group (BC, n=13) or with bone-cement enforced by Vicryl mesh in another group (BCVM, n=13) in osteoporosis-like saw bone blocks. Pullout testing was subsequently performed. In a second experimental phase, similar experiments were performed using human cadaveric lumbar vertebrae (n=10). In osteoporosis-like saw bone blocks, a mean screw pullout force of 350N (±125) was significantly higher with the Bone cement (BC) compared to bone-cement enforced by Vicryl mesh (BCVM) technique with 240N (±64) (p=0.030). In human cadaveric lumbar vertebrae the mean screw pullout force was 784 ± 366N with BC and not statistically different to BCVM with 757 ± 303N (p=0.836). Importantly, cement extrusion was only observed in the BC group (40%) and never with the BCVM technique. In vitro textile reinforcement of bone cement for pedicle screw augmentation successfully reduced cement extrusion compared to conventionally delivered bone cement. The mechanical strength of textile delivered cement constructs was more reproducible than standard cementing. This article is protected by copyright. All rights reserved

Keywords: Pedicle screw; augmentation; bone cement; Vicryl mesh; textile dowel

Introduction

Sufficient implant hold in osteoporotic, previously radiated or instrumented bone is technically and biologically difficult. This becomes increasingly clinically urgent, as epidemiological trends predict that more than half of the population in industrial countries will be older than 65 years by the year 2050 [1]. Accordingly, revision surgery rates in a previously instrumented spine will increase in the future [2]. Techniques to overcome the challenges of spinal instrumentation fixation in osteoporotic bone have included different kinds of pedicle screws, insertion angles [3, 4] or methods of cement augmentation. Polymethylmethacrylate (PMMA) augmentation is considered as a gold standard for enhancing screw hold and pullout strength in osteoporotic bones. Several studies investigating cement augmentation in transpedicular, vertebroplasty and kyphoplasty have reported inconsistent results [2, 5-8].

Unfortunately all cementing techniques are associated with the potential complication of cement extrusion, with secondary effects due to nerve or cord compression, cement embolisms, and/or technical difficulties in the event of revision surgery. Cement extrusions are not rare, with reported rates falling between 5% and 39% [9]. Clinical manifestations such as neurologic injury are fortunately less common [9]. Extrusion of cement with embolization has been however reported in 4% of cases [9-11]. Three leakage patterns are typically encountered: epidural through the basivertebral vein, intravascular through the segmental vein and intradiscal or extracortical through cortical defects [12]. The main contributor to cement extrusion is the pressure needed in applying the cement to the pedicle and the vertebra. One documented technique to minimize the extrusion of bone cement is to use partly cured cement, with however the disadvantage of less stability [7, 13]. Surgical revision of an instrumented vertebra with screw loosening, use of cementing in revision is even more challenging, as the sclerotic surface around the previously loosened screw may prevent hold at the cement-screw- bone interface.

In an effort to mitigate the potential for cement extrusion, we investigated the novel approach of preloading cement into a biomaterial mesh that is then delivered to a pre-drilled hole using an insertion tool. The intention was to minimize cement extrusion while exploiting increased cement plasticity in the initial phase of cementing. In this work we demonstrate that cement preloading into a textile mesh may offer a powerful and innovative method to minimize complications associated with cement extrusion in surgical situations where additional pedicle screw hold is needed.

Materials and Methods

To minimize effects due to variations in bone quality, we first tested the practicality of the approach using open-cell polyurethane foams as a test material. Synthetic foam with a density of five to ten pounds per cubic foot (pcf) has been shown to have material properties equal to osteoporotic bone [14-16]. Test blocks of 180x140x40mm saw bone (Sawbones®Worldwide, Vashon Island, Washington USA) with a 7.5pcf were therefore used in these experiments. The test blocks were predrilled with 6mm holes. A standard PMMA (Palacos®LV+G, Hereus Medical GmbH, Wehrheim, Germany) was used for bone augmentation and 6/40mm pedicle screws (USS II DePuy Synthes, Selzach, Switzerland) were used for pullout testing.

Two experimental groups were formed: In group one, the 6mm pedicle screws were augmented according to standard practice using bone cement (BC). Here, the predrilled holes of the test block were augmented with 2cc of PMMA before inserting the 6/40mm pedicle screws. The cement was squeezed into the hole. The amount of bone cement corresponds to volumes previously reported to achieve optimal pullout characteristics [17-19]. In group two, 2cc of bone cement was first applied to a 50x50mm Vicryl mesh (BCVM) (Ethicon Products, Johnson & Johnson, Spreitenbach, Switzerland) that was then inserted to the predrilled hole using a pointed rod before screwing in the 6/40mm pedicle screw. The mesh is widely available, relatively inexpensive, and resistant to bacteria bio film formation [20, 21].

Axial pullout tests were performed with a universal material testing machine (Zwick 1456, Zwick GmbH, Ulm, Germany) after cyclic application of orthogonal forces (20 cycles, ±5 N) on a 10cm lever arm. The other end of the lever was rigidly mounted on each pedicle screw to produce bending moments. Pullout testing was initiated with a preload of 5N and a constant displacement rate of 1mm/sec. The maximum pullout force was quantified. After pullout, the location of the bone cement was visually analysed and the corresponding void volume within the saw bone block was calculated.

In a second experimental phase, we repeated the pullout test with 10 fresh frozen human cadaveric lumbar vertebrae (Science Care, Phoenix, USA) after ethic committee approval. One specimen (L1-5) was from an 84 year old female, BMI 21.25 and osteoporosis. The second specimen (L1-5) was from an 83 year old female, BMI 22.14 and osteoporosis. The pedicles were predrilled with 6mm holes. In the first vertebra the predrilled holes were augmented on the left side with 2cc of PMMA before inserting the 6/40mm pedicle screws. On the right side 2cc of bone cement was applied to a 50x50mm Vicryl mesh and was then inserted to the predrilled hole with a pointed rod before insertion of 6/40mm pedicle screws (Fig. 1). On the following vertebrae the sides were switched regarding the cementing technique to receive five BC and BCVM augmented pedicle screws on the left and five from each technique on the right side. The initial torque for screw insertion was measured and a CT scan performed to visualize the cement location before pullout testing was done. Pullout testing was then performed and evaluated in the same manner as in the first trial phase.

Statistical analyses

Descriptive statistics were used to report means, standard deviations and ranges of data, where appropriate. Intergroup comparison of pullout forces was done using two tailed Students t-test and Fisher's exact test assuming normally distributed, parametric data, with a p-value of <0.05 defined as statistically significant.

Results

For the first trial with cellular foam the mean maximum pullout force in group one (BC; n=13) with standard bone cement augmented pedicle screws was 350 ± 125N. The pullout force ranges reached from 126 to 596N. In the second group (BCVM; n=13), the mean maximum force was 240 ± 64N. The pullout force range reached from 151 to 421N. There was a statistically significant difference between the two groups with a p-value of 0.030. Figure 2 shows the mean maximum force of both groups (BC and BCVM) with upper and lower quartiles and range of the measured results. There was a wider range of performances at the BC group with twice the SD (± 125N) compared to the BCVM group (± 64N). The bone cement was distributed more cylindrically along the entire length of the pedicle screw in the BC group and more conically in the BCVM group with more bone cement at the proximal part than at the distal part of the screw (Fig. 3). The saw bone block volume void after pullout was 19% greater in the BC group compared to the BCVM group. The volume reached from 3.8cc to 11.5cc in the BC group with a SD of 2.99. In the BCVM group the volume reached from 3.4cc to 6.1cc with a SD of 1.03.

In the second experimental phase with human cadaveric lumbar vertebrae the mean maximum pullout force in group one (BC; n=10) was 784 ± 366N. The pullout force ranges reached from 367 to 1434N. In the second group (BCVM; n=10) the mean maximum force was 757 ± 303N. The pullout force range reached from 306 to 1156N. There was no statistically significant difference between the two groups with a p-value of 0.836. Figure 4 shows the mean of maximum force in both groups (BC and BCVM) with their upper and lower quartiles and range of the measured results. There was a wider range of performances within the BC group with a SD of ± 366N compared to the BCVM group (± 303N). Four (40%) specimens with cement extrusion were found in the BC group with two extraforaminal cement extrusions and two extrusions into the spinal canal (Fig. 5). Cement extrusion into the transverse process was not considered as a clinically relevant extrusion. In contrast, no cement extrusion was documentable in the BCVM. This difference was statistically significant (p=0.043). Mean initial torque was below detection of the measurement device (< 0.01Nm) in the BC group and 0.11Nm in the BCVM group and was statistically significant (p=0.002). The failure mode was in each group 8 times a complete fracture of the pedicle and twice a screw pullout. The energy to failure, meaning the energy that the specimen has absorbed up to the point of specimen failure was 1535 ± 782Nmm in the BC group and 1963 ± 1075Nmm in the BCVM group (p=0.351).

The energy to failure is the area under the force-deflection curve from test start to the failure point, with higher values reflecting a more “tough vs. brittle” nature of mechanical failure.

Discussion

Cement augmentation with PMMA is regarded as the most reliable method to enhance pedicle screw pullout force in osteoporotic bone [2, 5]. Although modern PMMAs used in spinal surgery have a reduced exothermic polymerization reaction to minimize tissue necrosis and nerve damage, the problem of cement extrusion still persists [9-11, 22]. Modified cannulated pedicle screw to insert the cement more posteriorly demonstrated more often a cement leakage because of smaller holes with potentially much greater injection pressures [2, 5, 23]. Additionally, cementing is technically even more difficult in revision surgery with already previously instrumented pedicles and screw loosening and an enlarged sclerotic pedicle hole with a smooth surface. A reliable and safe method for cement augmentation has been lacking until now. The subject of this study was to investigating the potential of alternative and controlled delivery cement through the use of a textile mesh.

In first experimental tests using an open-cell polyurethane foam the mean maximal pullout force favored the standard cement technique (BC) with a mean maximal force of 350N compared to 240N in the BCVM group (p=0.030). However the BC group showed a wider range with nearly twice the SD compared to the BCVM group. Thus mechanical performance of the standard cementing approach could be considered as less reproducible. The qualitative analysis of the distribution of the PMMA around the screw showed a more cylindrical distribution around the pedicle screw in the BC group. In the BCVM group more of the bone cement tended to be localized at the proximal part of the screw. Accordingly, the calculated volume of the pulled out saw bone block was 19% greater in the BC group, underpinning the higher maximal pullout load in this group. These characteristics differed somewhat in human lumbar vertebrae. Studies have shown better fixation closer to the pedicle, as the pedicle contributes to around 60% of the pullout force and 80% of the cranio-caudal stiffness [24]. The second set of experiments in human cadaveric vertebrae was highly variable, and no conclusions regarding the mean maximal pullout load could be drawn. Still the failure mode in both groups was generally bone fracture rather than pullout, indicating that both methods yielded clinically adequate mechanical purchase. The energy to failure did tend to be higher in the BCVM group with 1963 ± 1075Nmm compared to in the BC group with 1535 ± 782Nmm, suggesting that the BCVM combination may potentially toughen the bone cement.

In both groups (BC/BCVM) soft PMMA was used. Several studies have demonstrated increased axial pullout strength for the soft cementing technique [7, 13]. Nevertheless the risk of PMMA leakage or embolization is higher at the soft stage of cementing [25]. In the first trial the nearly doubled standard deviations observed in the BC group may be explained with the use of soft PMMA and its unpredictable distribution within the trabecular bone. In contrast the soft cement in the BCVM technique is localized to the Vicryl mesh and was therefore likely to be distributed less freely. The void volumes within the saw bone block after pullout showed a nearly three times larger SD in the BC group, emphasizing the better predictability of BCVM technique. This phenomenon was confirmed in the sets of experiments with human cadaveric vertebrae, where the corticalis of the pedicle limits the cement distribution. Further, application of PMMA enforced Vicryl mesh using dowel insertion to a preexisting hole requires less pressure with therefore reduced risk of cement leakage or embolization. Accordingly, no case of cement extrusion was seen in CT in the BCVM group.

Among the limitations of the experimental models is reliance on ex-vivo biomechanical testing in sawbones and human cadaveric lumbar vertebrae in only two specimens. Further, primary stability was only assessed by axial pullout forces to single pedicle screws and other situations with angulated forces were not been investigated. Another limitation that requires additional study is that fact that potentially adverse biological effects on bone biology induced by the Vicryl mesh are yet unknown. Despite these limitations, we believe that the technique we have newly introduced warrants attention, as its potential clinical benefit might be considerable.

Conclusion

The method of BCVM enforcing of pedicle screws provides more controlled cement distributions, with improved mechanical reproducibility. Our in vitro experiments indicate that sufficient mechanical strength can be achieved with substantially lower risk of cement extrusion compared to the standard cementing technique. In vivo experiments are needed to investigate the feasibility, bio-compatibility and long term outcome of this promising new approach.

References

1. Riggs BL, Melton LJ. 1995. The worldwide problem of osteoporosis: insights afforded by epidemiology. Bone Nov17(5 Suppl)): 505S-511S.

2. Elder BD, Lo SF, Holmes C, Goodwin CR, Kosztowski TA, Lina IA, Locke JE, Witham TF. 2015. The biomechanics of pedicle screw augmentation with cement. Spine (Phila Pa 1976) Jun 1(15(6)): 1432-45.

3. Farshad M, Farshad-Amacker N, Bachmann E, Snedeker JG, Schmid SL. 2014. Biomechanical comparison of sagittal-parallel versus non-parallel pedicle screw placement. Acta Neurochir (Wien) No156(11): 2147-51.

4. Barber JW, Boden SD, Ganey T, Hutton WC. 1998. Biomechanical study of lumbar pedicle screws: does convergence affect axial pullout strength? J Spinal Disord Jun 11(3): 215-20.

5. Becker S, Chavanne A, Spitaler R, Kropik K, Aigner N, Ogon M, Redl H. 2008. Assessment of different screw augmentation techniques and screw designs in osteoporotic spines. Eur Spine J Nov17(11): 1462-9.

6. Burval DJ, MaLain RF, Milks R, Inceoglu S. 2007. Primary pedicle screw augmentation in osteoporotic lumbar vertebrae: biomechanical analysis of pedicle fixation strength. Spine (Phila Pa 1976) May 1(32(10)): 1077-83.

7. Linhardt O, Lüring C, Matussek J, Hamberger C, Plitz W, Grifka J. 2006. Stability of pedicle screws after kyphoplasty augmentation: an experimental study to compare transpedicular screw fixation in soft and cured kyphoplasty cement. J Spinal Disord Tech Apr19(2):87-91.

8. Halvorson TL, Kelley LA, Thomas KA, Whitecloud TS, Cook SD. Effects of bone mineral density on pedicle screw fixation. 1994. Spine (Phila Pa 1976) Nov 1(19(21)): 2415-20.

9. Kerry G, Ruedinger C, Steiner HH. 2013. Cement embolism into the venous system after pedicle screw fixation: case report, literature review, and prevention tips. Orthop Rev (Pavia) Sep12;5(3): e24

10. Röllinghoff M, Siewe J, Eysel P, Delank KS. 2010. Pulmonary cement embolism after augmentation of pedicle screws with bone cement. Acta Orthop Belg Apr76(2): 269-73.

11. Temple JD, Ludwig SC, Ross WK, Marshall WK, Larsen L, Gelb DE. 2002. Catastrophic fat embolism following augmentation of pedicle screws with bone cement : a case report. J Bone Joint Surg Am Apr84-A(4): 639-42.

12. Yeom JS, Kim WJ, Choy WS, Lee CK, Chang BS, Kang JW. 2003. Leakage of cement in percutaneous transpedicular vertebroplasty for painful osteoporotic compression fractures. J Bone Joint Surg Br Jan85(1): 83-9.

13. Flahiff CM, Gober GA, Nicholas RW. 1995. Pullout strength of fixation screws from polymethylmethacrylate bone cement. Biomaterials May16(7): 533-6.

14. Chapman JR, Harrington RM, Lee KM, Anderson PA, Tencer AF, Kowalski D. 1996. Factors affecting the pullout strength of cancellous bone screws. J Biomech Eng Aug118(3): 391-8.

15. Poukalova M, Yakacki CM, Guldberg RE, Lin A, Saing M, Gillogly SD, Gall K. 2010. Pullout strength of suture anchors: effect of mechanical properties of trabecular bone. J Biomech Apr19(43(6)):1138-45.

16. Ramaswamy R, Evans S, Kosashvili Y. 2010. Holding power of variable pitch screws in osteoporotic, osteopenic and normal bone: are all screws created equal? Injury Feb41(2): 179-83.

17. Chen YL, Chen WC, Chou CW, Chen JW, Chang CM, Lai YS, Cheng CK, Wang ST. 2014. Biomechanical study of expandable pedicle screw fixation in severe osteoporotic bone comparing with conventional and cement-augmented pedicle screws. Med Eng Phys Nov(36(11)): 1416-20.

18. Fölsch C, Goost H., Figiel J, Paletta JR, Schultz W, Lakemeier S. 2012. Correlation of pull-out strength of cement-augmented pedicle screws with CT-volumetric measurement of cement. Biomed Tech (Berl) Dec57(6): 473-80.

19. Yan YB, Teo EC, Qiu TX, Wu ZX, Qi W, Liu D, Lei W. 2013. Finite element study on the amount of injection cement during the pedicle screw augmentation. J Spinal Disord Tech Feb26(1): 29-36.

20. Nyame TT, Lemon KP, Kolter R, Liao EC. 2011. High-throughput assay for bacterial adhesion on acellular dermal matrices and synthetic surgical materials. Plast Reconstr Surg 128: 1061-1068.

21. Tessler O, Reish RG, Maman DY, Smith BL, Austen WG Jr. 2014. Beyond biologics: absorbable mesh as a low-cost, low-complication sling for implant-based breast reconstruction. Plast Reconstr Surg Feb133(2): 90e-9e.

22. Belkoff SM, Molloy S. 2003. Temperature measurement during polymerization of polymethylmethacrylate cement used for vertebroplasty. Spine (Phila Pa 1976) Jul15(28(14)): 1555-9.

23. Renner SM, Lim TH, Kim WJ, Katolik L, An HS, Andersson GB. 2004. Augmentation of pedicle screw fixation strength using an injectable calcium phosphate cement as a function of injection timing and method. Spine (Phila Pa 1976) Jun1(29(11)): E212-6.

24. Hirano T, Hasegawa K, Takahashi HE, Uchiyama S, Hara T, Washio T, Sugiura T, Yokaichiya M, Ikeda M. 1997. Structural characteristics of the pedicle and its role in screw stability. Spine (Phila Pa 1976) Nov1(22(21)): 2504-10.

25. Bohner M, Gasser B, Baroud G, Heini P. 2003. Theoretical and experimental model to describe the injection of a polymethylmethacrylate cement into a porous structure. Biomaterials Jul24(16): 2721-30.

Figure 1: Methodical illustration of pullout testing of pedicle screw augmentation with cemented mesh

Figure 2: Mean of maximum force in both groups (BC and BCVM) with their upper and lower quartiles and range of the measured results of BC and BCVM enforced pedicle screws in open cellular foam

Figure 3: Cement localization after pullout testing with BC and BCVM enforced pedicle screws in open cellular foam

Figure 4: Mean of maximum force in both groups (BC and BCVM) with their upper and lower quartiles and range of the measured results of BC and BCVM enforced pedicle screws in human cadaveric lumbar vertebrae

Figure 5: Example of cement extrusion into the spinal canal with BC enforced pedicle screws

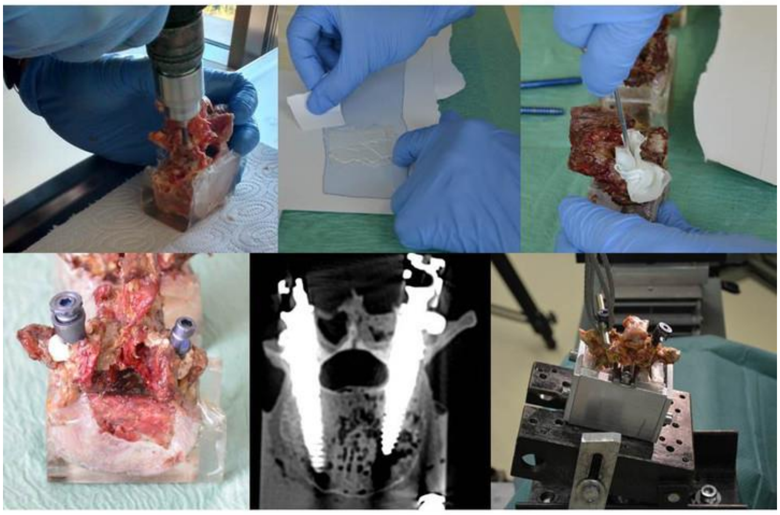

Figure 1

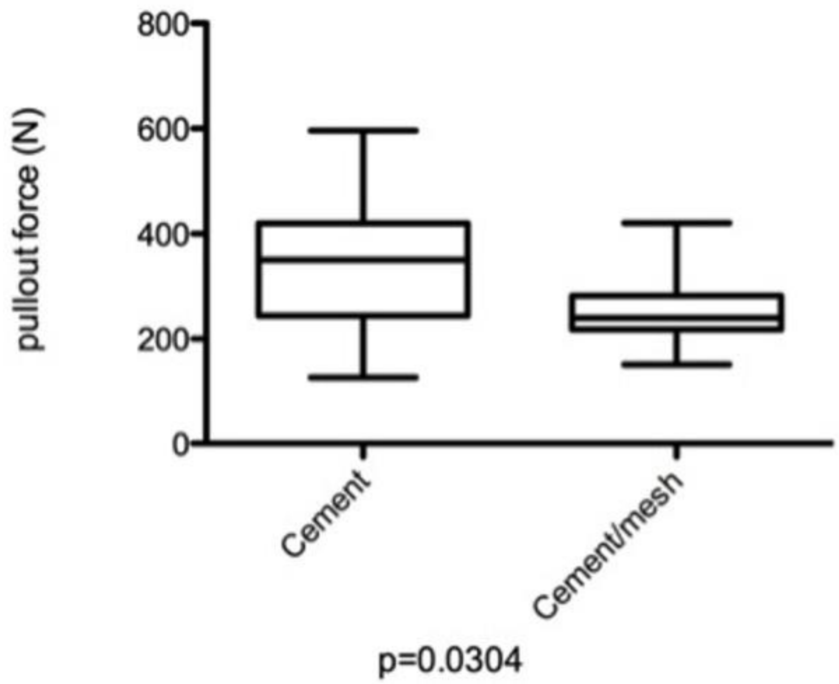

Figure 2

Figure 3

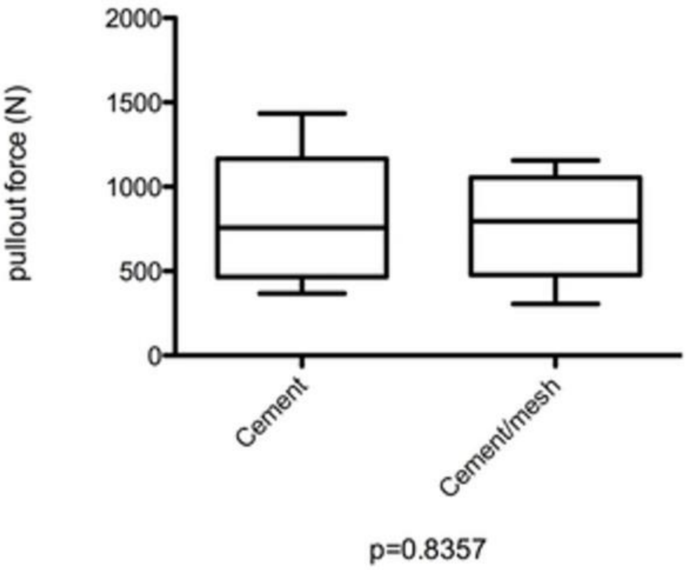
2000
1500
1000
500
0
pullout force (N)
Cement
Cement/mesh
p=0.8357

Figure 4

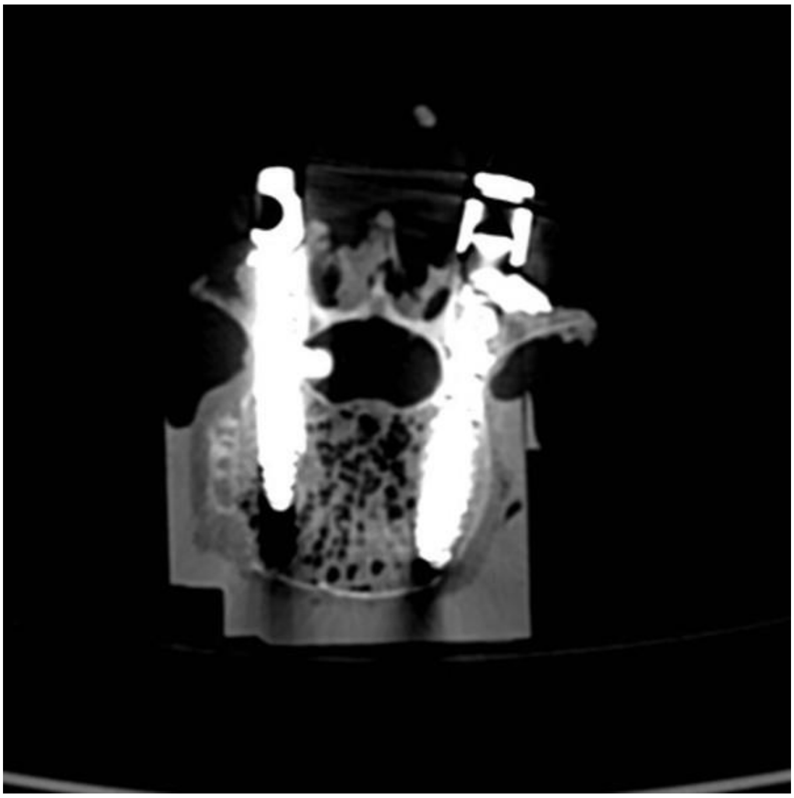

Figure 5